

## **REMARKS**

### **Status of the Claims**

Claims 1-24, 26-28 and 30-45 are currently pending in the application. Claims 21-24, 26-28, 30-39 and 42-45 stand rejected. The Examiner objects to claim 31. Claims 1-20, 40 and 41 are withdrawn as being drawn to a non-elected invention. Claims 21-23, 26 and 31 have been amended without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendment to claims 21-23 are supported by the specification at, for instance, Examples 18 and 19 of the specification, at pages 54-57, and as explained in further detail, below. Amendment of claim 26 is to clarify what features comprise the DNA and to remove reference to SEQ ID NO:22. Reconsideration is respectfully requested.

### **Objections to the Claims**

The Examiner objects to claim 31. (*See*, Office Action of October 31, 2007, at page 2, hereinafter, "Office Action"). The Examiner states that claim 31 is missing the phrase "according to." Applicants have added the words "according to" back to claim 31. Claim 31 has been further amended to recite, in part, "claims 21 through 23" instead of "claims 21 to 23." This is merely a clarifying amendment and does not in any way alter the scope of claim 31.

Reconsideration and withdrawal of the objection to claim 31 are respectfully requested.

### **Rejections Under 35 U.S.C. § 103(a)**

Claims 21-24, 26-28, 30-39 and 42-45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Liu et al., U.S. Patent Application Publication No. 2002/0137211,

(hereinafter, "Liu et al."), in view of Zhao et al., *Acta Biochimica et Biophysica Sinica*, 33(1):112-116, 2001 (hereinafter, "Zhao et al."), Zhang et al., *Acta Biochimica et Biophysica Sinica*, 31(2):119-123, 1999 (hereinafter, "Zhang et al."), and GenBank Acc. No. AF226688. (See, Office Action, at pages 4-8). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that Applicants' previous arguments presented in their reply of August 17, 2007 were considered but were unpersuasive because Applicants failed to consider what the combined disclosures of all the cited references would have suggested to one of ordinary skill in the art, rather than arguing against the disclosures individually. (*Id.* at page 4).

Although Applicants do not agree that the presently claimed invention is obvious in light of the combined disclosures of the cited references, to expedite prosecution, claims 21-23 have been amended herein without prejudice or disclaimer to additionally recite, in part, "(2) an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688." None of the cited references disclose or fairly suggest this unique feature.

Support for the amendment of claims 21-23 may be found at Examples 18 and 19. Examples 18 and 19 show that the construct "HUP-IC-HA," in which a gene cassette contains a roughly 5.5 kbp upstream region from a fibroin H chain gene promoter, yields a surprisingly increased amount of expression of an exogenous protein (feline interferon- $\omega$ ) as compared to other constructs without this insert. In addition, the present specification, on page 10, line 36 to page 11, line 2, which explains Fig. 19, showing the amount of expression of an exogenous protein by HUP-IC-HA, states that "[i]n addition, a gene region that improves the amount of protein produced was found in a roughly 5.5 kbp upstream region from fibroin promoter."

Similarly, the specification, on page 11, lines 8 to 11, which explains Fig. 19, showing the amount of expression of an exogenous protein by HUP-IC-HA, states that “[i]n addition, a gene region that improves the amount of protein produced was reconfirmed in a roughly 5.5 kbp upstream region from fibroin promoter.” Therefore, the fact that the high expression of an exogenous protein is caused by “a roughly 5.5 kbp upstream region from a fibroin H chain gene promoter” is fully supported by this description in the present specification.

By this amendment the claimed gene cassette is limited to only that which provides a high expression of an exogenous protein. Regarding the expression of an exogenous gene (feline interferon- $\omega$ ) in the posterior silk gland tissue, a gene cassette after the amendment, i.e., “HUP-IC-HA” which contains “an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688,” and a gene cassette before the amendment, i.e., “HP-IC-HA” which does not contain “an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688” were compared in Example 18. As shown in Fig. 18, regarding the amount of expression of an exogenous protein (feline interferon- $\omega$ ), a gene cassette after the amendment, i.e., “HUP-IC-HA” which contains “an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688” is clearly superior in comparison with a gene cassette before the amendment, i.e., “HP-IC-HA” which does not contain “an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688.”

In addition, regarding the expression of an exogenous gene (feline interferon- $\omega$ ), in the silk thread, the above-mentioned two gene cassettes were compared in Example 19. As shown

in Fig. 19, regarding the amount of expression of an exogenous protein (feline interferon- $\omega$ ), a gene cassette after the amendment, i.e., "PUP-IC-HR" which contains "an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688" is superior in comparison with a gene cassette before the amendment, i.e., "HP-IC-HA" which does not contain "an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688."

In addition, none of the references to which the Examiner cites describe or fairly suggest that feature of "an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688" placed in a cassette between "a piggyback transposon" and "a fibroin H chain gene promoter" or that such a feature would enhance the amount of expression of an exogenous protein.

Since no independent reasoning is provided by the Examiner for the rejection of dependent claims 24, 26-28, 30-39 and 42-45, these dependent claims are believed to be non-obvious in light of the combined disclosures of the cited references for, *inter alia*, depending from one or more non-obvious base claims, amended claims 21-23.

Reconsideration and withdrawal of the obviousness rejection of claims 21-24, 26-28, 30-39 and 42-45 are respectfully requested.

### ENTRY OF AMENDMENTS

The amendments to the claims should be entered by the Examiner because the amendments are supported by the as-filed specification and do not add any new matter to the

application. Additionally, the amendments should be entered since they comply with requirements as to form, and place the application in condition for allowance. Further, the amendments do not raise new issues or require a further search since the amendments incorporate elements from dependent claims into independent claims and/or are supported by the as-filed specification. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested since they certainly remove issues for appeal.

### CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 

Andrew D. Meikle

Registration No.: 32,868

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicants

